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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,260	03/22/2004	Jeffrey S. Kiel	455-023	1934

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	**PAPER NUMBER**
1621	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,260	KIEL ET AL.	
	Examiner	Art Unit	
	Yevgeny Valenrod	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 20-29) in the reply filed on 26th of May 2006 is acknowledged. In light of applicants' argument, Groups I and II have been rejoined and will be examined together. Restriction requirement between groups II and III as product and a method of use stands. The traversal of restriction between groups II and III is on the ground(s) that issuing patents on both product and process of use claims is common in the USPTO. This is not found persuasive because 1) it is at the discretion of the examiner to determine if examination of claims presents a search burden 2) when product and process of use claims are restricted and the applicants subsequently chooses the product claims, the process claims are rejoined if the product claims are found allowable (as is the case with the instant application), which can result in a patent being issued with both product and process claims in it. Examiner respectfully reminds the applicant of the considerations for rejoinder:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL. Non-elected claims of group III are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,383,471) in view of Gordziel (US 6,287,597).

Scope of prior art

Chen et al. discloses the general teaching of converting an active pharmaceutical ingredient such as gabapentin (column 6, line 33) into its tannate salt complex (column 11 line 50) by protonating the basic groups of gabapentin. Furthermore, the ionizing agent is present in an amount of at least 0.1 mole equivalent per mole of ionizable functional groups (column 11, lines 56-59)

Ascertaining the difference between the prior art and the claims at issue

Chen et al. teach converting gabapentin into gabapentin tannate. The instant invention differs from the prior art reference in that the reference fails to disclose addition of dispersing agent, excipients, pH ranges and addition of sweeteners.

Secondary reference

Gordiziel teaches a pharmaceutical composition that comprises: Pyrilamine Tannate, Pectin, Sucrose, Saccharin Sodium, Magnesium Aluminum Silicate, Water, Glycerin and Methylparaben. (column 3, Example 2). Gordiziel also teaches suspensions of the compositions and solid forms of the compositions (column 2, lines 15-22)

Obviousness

Chen et al. teach a method of producing gabapentin tannate. In order to administer the active ingredient it is common in the art to add physiologically inactive ingredients such as sweetening agents, preservatives, thickening agents, suspending agents, flavoring agents. Gordziel provides an example of a tannate salt being used in a composition that comprises all of the excipients claimed by the applicant. One of ordinary skill in the art would have been motivated to combine the method of producing gabapentin tannate as described by Chen et al with the excipients utilized by Gordzil, in order to prepare a pharmaceutical composition.

As to the pH range of 2-11 as claimed by the applicant in claim 18. A person of ordinary skill in the art would appreciate the a combination of any of the above excipients with tannic acid or gabapentin or gabapentin tannate would have a pH in the range of 2-11.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 6, 8, 10-14, 19-25, 27 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 of copending Application No. 10/805,806. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The claims correspond as follows: (instant claim/copending application claim) 1/1; 2/1,2; 3/3; 4/1; 6/9; 8/10; 10/8; 11/8; 12/7; 13/9; 14/9; 19/9; 20/11; 21/12; 22/13; 23/14; 24/13; 25/15; 27/16; 28/11.

Non-statutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9, 12-14 and 18 of copending Application No. 10/806,022 in view of Gordziel (US 6,287,597). This is a provisional obviousness-type double patenting rejection.

Instant application claims a process for preparing a pharmaceutical composition comprising reacting gabapentin with tannic acid to produce gabapentin tannate. The same process includes the following limitations as mentioned in various dependant claims: tannic acid of natural or synthetic origin, one or more excipients (includes dispersing agent, suspension agents, sweetening agents), composition ratios, solvent, and pH range.

Scope of the Copending Application

Copending application No. 10/806,022 claims a process for preparing gabapentin tannate (claim 6), various methods of mixing the reagents (claims 7-9), tannic acid to gabapentin ratio of .1:1 to 10:1, maintaining the pH between 2 to 11 (claim 13) and 0.05% to 40% of the reactive mixtures composition consisting of tannic acid.

Ascertaining the difference between the claims of the copending application and the instant claims

Although Copending application No. 10/806,022 claims a process for preparing gabapentin tannate, it fails to claim a pharmaceutical composition comprising excipients as described in the instant claims.

Secondary reference

Gordiziel teaches a pharmaceutical composition that comprises: Pyrilamine Tannate, Pectin, Sucrose, Saccharin Sodium, Magnesium Aluminum Silicate, Water, Glycerin and Methylparaben. (column 3, Example 2).

Motivation to combine

Copending application No. 10/806,022 claims a method of producing gabapentin tannate. In order to administer the active ingredient it is common in the art to add physiologically inactive ingredients such as sweetening agents, preservatives, thickening agents, suspending agents, flavoring agents. Gordziel provides an example of a tannate being used in a composition that comprises all of the excipients claimed by the applicant. One of ordinary skill in the art would have been motivated to combine the method of producing gabapentin tannate as described in the copending application with the excipients utilized by Gordiziel, in order to prepare a pharmaceutical composition.

Conclusion

Claims 1-32 are pending in the application

Claims 30-32 are withdrawn as non-elected claims

Claims 1-29 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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